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Definition of an HMO that is not Federally Qualified and description of how the HMO must meet the Federal requirements.

The attached Chapter 1229, Health Maintenance Organization Services, Section 1229.2, defines Health Maintenance Organizations (HMOs).

The HMO that is not federally qualified, must meet at least the following requirements of 42 CFR 434.20(c)(1)(2)(3):

- I. **Be organized primarily for the purpose of providing health care services.**
 - A. Each application for a Certificate of Authority under the Act shall be made to the Secretary and the Commissioner in writing. The part of the application directed to the Secretary should contain the information noted in the attached 28 PA Code, Chapter 9, Health Maintenance Organization, Annex C, Application For Certificate of Authority, Subsection 9.52, Content of Application for Certificate of Authority (1)-(22), and 31 PA Code, Chapter 301, Health Maintenance Organization, Subchapter C, Application for Certificate of Authority, Subsection 301.42, Content of Application for Certificate of Authority, (1)-(23), and 40 PA Code, Subsection 1555.1, Certificate of Authority.
 - B. A corporation receiving a Certificate of Authority to establish and operate a health maintenance organization shall provide quality health care services in a cost effective manner which does not impair the corporation's ability to deliver, arrange for the delivery, or pay for health services for its members. Attached are 31 PA Code, Chapter 301, Subchapter D, Operational Standards for a Health Maintenance Organization, Subsection 301.61, Operational Standards, and 28 PA Code, Chapter 9, Subchapter E, Operational Standards for a Health Maintenance Organization, Subsection 9.71, Operational Standards for a Health Maintenance Organization.

JUL 30 1992

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Definition of an HMO that is not Federally Qualified and description of how
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II. Make the services it provides to its Medicaid enrollees as accessible to them (in terms of timeliness, amount, duration, and scope) as those services are to nonenrolled Medicaid recipients within the area served by the HMO.

- A. A health maintenance organization shall have and maintain adequate arrangements for assurance of access to care as noted in the attached 28 PA Code, Chapter 9, Annex A, Subchapter E, Operational Standards for a Health Maintenance Organization, Subchapter 9.75, Assurance of Access to Care, (a)-(f).
- B. Health maintenance organization shall provide either directly or through arrangements with others basic health services and physician services pursuant to 40 PA Code, Subsection 1554, Services Which Shall Be Provided, (a)-(b).
- C. A health maintenance organization shall provide at least the basic health services as listed in 28 PA Code, Chapter 9, Annex A, Subchapter E, Operational Standards for a Health Maintenance Organization, Subsection 9.72, Basic health services, (a)-(d).

JUL 30 1992

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Definition of an HMO that is not Federally Qualified and description of how the HMO must meet the Federal requirements.

III. Make provision, satisfactory to the Medicaid agency, against the risk of insolvency, and assure that Medicaid enrollees will not be liable for the HMO's debt if it does become insolvent.

- A. The 31 PA Code, Chapter 301, Health Maintenance Organization, Subsection 301.2 and Subchapter G, Subsections 301-121 - 301.126 implements several consumer protection measures to mitigate HMO insolvencies and provides for other protection in the event of an HMO insolvency.

TN #92-01
Supersedes
TN #84-2

Approval Date JUL 30 1992 Effective Date _____

RULES AND REGULATIONS

Contact Person

Herb Rochman, Bureau of Financial Management, Office of the Budget, P. O. Box 1323, Harrisburg, Pa. 17105
717-787-5626.

The Office of the Budget finds:

(1) That public notice of intention to promulgate these administrative regulations have been duly given under sections 201 and 202 of the CDL (45 P. S. §§ 1201 and 1202) and the regulations thereunder, 1 Pa. Code §§ 7.1 and 7.2.

(2) That the establishment of the regulations is both necessary and appropriate for the administration and enforcement of the authorizing statute.

The Office of the Budget, acting under the authorizing statute, orders:

(1) The regulations of the Offices of Administration and the Budget, 4 Pa. Code Chapter 2, are amended to add Subchapter B, §§ 2.31 - 2.40, to read as set forth at 13 Pa. B. 1961 (June 18, 1983).

(2) The Secretary of the Budget shall submit this order and 13 Pa. B. 1961 to the General Counsel and the Attorney General for approval as to legality as required by law.

(3) The Secretary of the Budget shall duly certify this order and 13 Pa. B. 1961 and deposit the same with the Legislative Reference Bureau as required by law.

(4) This order shall take effect upon publication in the *Pennsylvania Bulletin*.

By the Office of the Budget

ROBERT BITTENBENDER,
Secretary

Fiscal Note: Fiscal Note 9A-3 remains valid for the final adoption of the subject regulation.

INDEPENDENT REGULATORY REVIEW COMMISSION

On June 8, 1983, the Independent Regulatory Review Commission received the proposed regulations from the Governor's Office of the Budget. These proposed regulations would amend 4 Pa. Code by adding §§ 2.31 - 2.40, concerning the payment of interest penalties to qualified small business concerns. This new subchapter is being proposed under the Office of the Budget's authority granted by the act of December 13, 1982 (Act 266), amending an act of 1929 (P. L. 343, No. 176) known as The Fiscal Code. This proposed regulation was published in the *Pennsylvania Bulletin* on June 18, 1983, with a 20-day comment period.

TN #92-01

Supersedes

TN #84-2

In some cases, the Commonwealth agencies have not been paying vendor's invoices promptly. This has resulted in a monetary hardship upon the vendors and can be a particular hardship on small business concerns. Because of this hardship, many small businesses are reluctant to bid on or seek Commonwealth contracts. The purpose of the proposed regulations is to insure that small businesses will not have to bear an unreasonable financial burden when doing business with the Commonwealth and to encourage all Commonwealth agencies to promptly pay vendors.

A letter was received from the Senate Appropriations Committee on June 21, indicating that the Committee would not be holding a meeting to discuss the regulations. On June 28, a letter was received from the House Appropriations Committee indicating that they approved the proposed regulations.

We have reviewed the proposal and find it to be in the public interest. Adoption of this new subchapter will encourage small businesses to compete for contracts with the State without having to worry about adverse cash flow impacts that could occur in the event of slow payment by the State. Similarly, the regulations should provide an incentive for all State agencies to promptly pay properly completed invoices and should improve the fiscal operation and reputation of the Commonwealth. There will be a small increase in the paperwork that these small businesses will have to complete since they will have to add on each invoice the self-certifying statement that they are a qualifying small business, but this burden should be insignificant. Likewise, there should be minimal fiscal impact upon the Commonwealth due to procedures being implemented by all State agencies to promptly pay outstanding obligations in a timely manner. There should be no adverse impact upon local governments or the general public. Therefore, we approve the proposed regulations as published at 13 Pa. B. 1961.

The Commission reserves the right to review these regulations if it is substantially amended prior to final publication.

Copies of this order shall be directed to the Secretary of the Office of the Budget, the chairmen of the Standing Committees, the Governor's Task Force on Regulatory Relief, the Attorney General, and the Legislative Reference Bureau.

Dated this 29th day of June, 1983.

Supplement I to
ATTACHMENT 2.1-A

Page 1

2391

IRVING G. ZIMMERMAN,
Chairman

[Pa. B. Doc. No. 83-1039 Filed August 5, 1983.
9:00 a.m.]

Title 28—HEALTH AND SAFETY

DEPARTMENT OF HEALTH

[28 PA. CODE CH. 9]

Health Maintenance Organizations

The Department of Health by this order adopts amendments to 28 Pa. Code by adding Chapter 9 (relating to health maintenance organizations) as set forth in Annex A.

The amendments were adopted under the Health Maintenance Organization Act, the act of December 29, 1972 (P. L. 1701, No. 364) as amended by the act of December 19, 1980 (P. L. 1300, No. 234) (40 P. S. §§ 1551 - 1567), particularly section 5.1(a), and sections 2102(a) and (g) of The Administrative Code of 1929 (71 P. S. §§ 532(a) and (g)).

The regulations are intended to protect subscribers who voluntarily enroll in health maintenance organizations, which combine the delivery and financing of health care.

Notice of proposed rulemaking was published at 11 Pa. B. 2490 (July 11, 1981), and the public was invited to comment.

The comments and the Department's response to those comments are summarized below:

1. Section 9.2. Definitions.

a. *Comment:* The terms "Individual practice association" (IPA), "Group/staff model HMO", and "Outpatient and preventive medical services" should be defined.

Response: The terms IPA HMO and Group/Staff Model HMO have been defined in the definitions section. "Outpatient and preventive medical services" has been more specifically defined in § 9.72, since this is the section in which detailed requirements for provision of basic health services are described.

2. Section 9.52. Content of application of certificate of authority.

a. *Comment* § 9.52(15): Job description for other than the HMO Medical Director should be required.

Response: The Medical Director within an HMO plays an important and pivotal role in ensuring the quality

PENNSYLVANIA BULLETIN, VOL. 13, NO. 32, SATURDAY, AUGUST 6, 1983

Approval Date

Effective Date

2392

RULES AND REGULATIONS

of care provided to subscribers. The job description is required so that it may be evaluated against Medical Director standards found in § 9.76(b). Since the regulations contain no standards for other senior management positions such as Executive Director or Marketing Director, job descriptions are not required for these positions.

In addition, the Department has determined that in the interest of clarity, the other items of information requested in § 9.52(15) should be listed separately and therefore reads as follows:

(15) A copy of proposed general subscriber literature.

(16) A job description for the position of medical director.

(17) A procedure for referral of subscribers to nonparticipating specialists.

(18) Written procedures for payment of emergency services provided by other than a participating provider.

Items 16 through 19 are subsequently renumbered 19 through 22.

b. *Comment, § 9.52(4):* An applicant should also be required to provide information regarding proposed practice site locations and hours of operation as this relates to the notions of accessibility and availability of services.

Response: The Department agrees and has added this requirement as a part of revised § 9.52(10).

3. Section 9.53(f):

a. *Comment:* The reasons why the Department would hold a public hearing should be specified. The relationship between the Health and Insurance Departments should be explained.

Response: This Section has been clarified to indicate that the reason for public hearings would be to gather additional information and that the Department will attempt to hold joint hearings with the Insurance Department wherever possible. The Department has further clarified § 9.53(f)(2) to indicate that notice will be published at least 10 days prior to the hearing.

4. Section 9.72. Operational standards regarding basic health services:

A. *Comment, § 9.72(a)(5):* The services required in subsection (a)(5) should be specified.

Response: Outpatient and preventive medical services has been more specifically defined by the addition of the phrase, "...such as well baby

care, immunizations, and periodic physical examinations."

b. *Comment, § 9.72(a)(2) and (a)(4):* The phrase, "or authorized by a primary care physician and performed by other licensed health professional(s) within their scope of practice" should be inserted in subsection (2) and (4) of 9.72(a).

Response: Addition of this phrase is unnecessary since the current language, "performed, prescribed, or supervised by a physician is sufficient."

5. Section 9.72(b):

The Department has initiated a change to make the copayment limitations applicable only to basic health services. This change is intended to give HMOs providing supplementary health services such as dental coverage or prescription drug coverage flexibility in competing in the health insurance marketplace. The Department has further clarified the final portion of § 9.72(b)(2) to read, "subscriber must demonstrate that co-payments in that amount have been made during the calendar year."

6. Section 9.73. Operational standards regarding subscriber grievance systems.

a. *Comment, General:* There should be provision for provider grievances.

Response: The appropriate method for resolving grievances between providers and an HMO is through the provider contract which is the instrument defining the relationship between the two entities.

b. *Comment, General:* HMOs should have more flexibility in structuring grievance systems.

Response: The Department strongly believes that some specific standards must be provided in order to safeguard subscriber interests. Establishment of more than two levels of review, for example, could act as a deterrent for consumers to file or pursue grievances through various layers of HMO bureaucratic appeal processes. The requirement that one-third of the grievance committee be subscribers is minimal, and serves to ensure that the subscriber viewpoint is present on the grievance committee.

It is noted that HMOs may gain flexibility in structuring grievance processes by utilizing the procedures found in § 9.97, relating to exceptions. The Department recognizes that a broad range of innovative grievance systems might be attempted which would meet the needs of a given organ-

ization. Thus, the Department intends to be flexible in its administration of this Section and will consider alternative grievance resolution systems under the "Exceptions" section. Also, it is noted that one person grievance committees are permitted under the provisions of § 9.73(1)(i).

c. *Comment, § 9.73(1)(i):* The grievance process should be revised to allow the involved provider also to present testimony.

Response: While the Department believes that, of necessity, provider/HMO relationships typically are such that a provider involved in a grievance would have adequate opportunity to provide input into the grievance process, the Department has amended § 9.73(1)(ii) so as to specifically permit both the subscriber and "any other party of interest" to submit written information in the grievance process.

d. *Comment, § 9.73(2)(iii):* This subsection should be clarified to note that grievances can be appealed to either the Health or Insurance departments.

Response: The subsection has been amended to read, "...be binding unless the subscriber appeals the decision, depending upon the nature of the grievance, to the Secretary or to the Commissioner." It is anticipated that grievances relating to quality of care would be handled by the Health Department, while grievances relating to contractual benefits would be handled by the Insurance Department. In actual practice, it makes little difference to which Department a subscriber appeals a decision, since the departments will cooperate in ensuring that grievance appeals received will be handled by the more appropriate Department.

7. Section 9.74. Operational standards regarding quality assurance systems.

a. *Comments, § 9.74(a)(2):* Section 9.74(a)(2) should allow HMOs to offer coverage for non-medically necessary services.

Response: The language of § 9.74(a)(2) has been changed to allow an HMO flexibility in providing non-medically necessary services if it so chooses.

8. Section 9.75. Operational standards regarding assurance of access to care

a. *Comment, General:* HMOs should be provided flexibility to reflect local conditions. Subsection (c)(1) is in direct conflict with the policy of the Pennsylvania Medical Society.

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RULES AND REGULATIONS

Response: The Department strongly believes that the requirement that nonemergency referrals for specialty care be approved by the subscriber's primary care physician is absolutely essential for cost and quality control within an HMO setting. The Department believes that no organizational arrangement is as important in characterizing an HMO as is the very special, desirable and key role played by the subscriber's voluntarily selected primary care physician. The primary care physician plays the ideal role of acting as the medical manager of the subscriber, ensuring that patients receive care of the best quality which is integrated, continuous and which is the most cost-effective for all parties concerned — the HMOs, its subscribers, and its participating physicians. The system makes best use of the primary care physician and of the specialist. It allows specialist physicians participating in an HMO to make the most effective use of their skills in treating patients who are really in need of a level of care commensurate with their training and experience. It likewise places a necessary control upon consumers who, through ignorance or otherwise, may make unnecessary demands upon the HMO's health care delivery system. Notwithstanding local referral practices, to allow the consumer to self-refer would defeat the purpose of the HMO system.

b. *Comment, § 9.75(d)(1):* This subsection needs clarification as to the extent of the requirement.

Response: It is not feasible to be more specific as to the extent of this specialist participation requirement because of the differing circumstances of HMOs and potential HMOs throughout the Commonwealth. In large urban areas of the State, an HMO would be expected to have formal arrangements for those specialties where services are limited. A rural HMO would be expected to have a formal procedure for providing needed specialist care, for most specialties, perhaps through appropriate referral to a tertiary care center.

c. *Comment, General:* The following section should be added: "If a health maintenance organization offers eye care which is within the scope of practice of optometry, it shall make optometric care available to its subscribers, and shall make the same reimbursement whether the service is provided by an optometrist or a physician."

Response: Optometric care is optional, not required, and since this language is already found in the statute,

it need not be repeated in regulation. See 40 P. S. § 1553.1(f).

d. *Comment, § 9.75(e)(1 — 5):* This Section should be rewritten and developed to describe written protocols governing general procedures to assure the availability of the services defined as minimal basic health services in 9.72(a)(1 — 5).

Response: The Department in its quest to ensure subscriber access to care, requires submission of written procedures describing how the applicant HMO is going to provide the listed services. These are "organizational protocols" not medical protocols as implied in the comment. The Department is seeking to learn about HMO preparedness in instructing its staff and participating providers in handling, for example, "treatment of chronic illnesses." In order not to confuse the request for general procedures with specific medical protocols for the treatment of a specific disease (for example, diabetes), the language of this Section has been changed to refer to procedures rather than protocols.

9. *Section 9.76. Operational standards regarding professional staffing of health maintenance organizations*

a. *Comment, § 9.76(a)(5):* There is great difficulty in applying staffing ratios to Individual Practice Association (IPA) Model HMOs.

Response: The requirement for IPA HMOs has been clarified by a revision of subsection (a)(5), which now reads, "An Individual Practice Association Health Maintenance Organization shall submit to the Department evidence of other standards or mechanisms which it applies to assure patient access to physicians as necessary to meet the intent of the above standards."

b. *Comment, § 9.76(a)(4):* The language appears to require Department approval to use physician extenders.

Response: Departmental approval for use of physician extenders was not intended. What was intended was Departmental approval to use physician extenders in order to meet the physician-subscriber ratio standards. Because the use of physician extenders is well accepted, the provision for Departmental approval has been deleted. The section now begins, "To meet physician-subscriber ratios, a health maintenance organization may use licensed and certified physician extenders. . . . Information regarding use of physician extenders to satisfy the professional standards is required to be submitted in the application for a certifi-

cate of authority, and this change has been reflected in § 9.76(a)(4)(i).

c. *Comment, § 9.76(a)(8):* (Now deleted). The Department should recognize the impact of continuing education programs on the professional competence of individuals is inconclusive.

Response: The Department has deleted the continuing education requirement. Most professional accrediting and credentialing bodies require continuing education, and to require continuing education in these regulations would be redundant and superfluous.

10. *Section 9.77. Operational standards regarding subscriber rights*

a. *Section 9.77(a)(5):* The Department has initiated a change to indicate that consent must be given unless the subscriber's medical condition prevents consulting with the subscriber, in accordance with section 103 of the Health Care Service Malpractice Act, 40 P. S. § 1301.103.

11. *Section 9.92. Quarterly reports:*

a. *Comment, General:* Quarterly reports are unnecessary and add to the administrative expenses of both the HMO and the Department. The Secretary is without authority to require submission of quarterly reports.

Response: The Department believes that the data required to be submitted in quarterly reports is minimal, relatively simple, to collect, and would be collected in any event by any well-managed HMO. Submission of such data on a quarterly basis is necessary so that the Department can monitor the data, compare it to general standards for HMO utilization, and compare data among HMOs. This will serve to act as an early warning system whereby significant under or over utilization of services can be promptly researched on an individual HMO basis in order to protect subscribers. Quarterly reports are currently submitted to the Department by all HMOs.

12. *Section 9.93. External quality assurance assessment*

a. *Comment, General:* This requirement seems unnecessary since the Secretary is without authority to assess the performance of HMOs. The Secretary is without authority to require an external quality assessment. The term "expert" should be clarified.

Response: This requirement is similar to the concept of having an independent certified public accountant audit a corporation's financial records or a JCAH team conduct a survey of a hospital's program. It allows the assessment to be done by experts which

RULES AND REGULATIONS

may not be available on the Health Department's staff, and permits the review to be conducted on a consultant basis with possible suggestions to be given for improvement of the quality assurance system. The National Committee for Quality Assurance, Washington, D.C. is an example of one organization which may be acceptable to the Department to conduct an external quality assurance assessment. This organization is composed of representatives of both group staff model HMOs and Individual Practice Association Model HMOs. The specific purpose of the organization is to assess HMO quality of care. It is the Department's opinion that it has adequate authority to require that such an external quality assessment be conducted on a periodic basis as a logical extension of its responsibility to monitor the quality of care provided to HMO subscribers. The Department also has made a minor clarification by specifically recognizing its right to require an external quality assessment if the Department receives indications of quality of care problems within a particular HMO.

13. Section 9.96. Board composition:

a. *Comment.* § 9.96(a): It is impossible to monitor influence of board members over other members.

Response: The Department has clarified that the undue influence requirement relates only to the subscriber selection process. The second sentence of subsection (a) now reads: "The subscriber board membership selection process shall be structured in such manner so as to prevent undue influence in the selection process by non-subscriber members of the board."

14. Section 9.97. Exceptions

a. *Comment, General:* HMOs need flexibility in structuring their functions and operations.

Response: In order to make it easier for HMOs to obtain an exception, the following phrase has been deleted from § 9.97(a), "... but when full compliance would create an unreasonable hardship on an applicant corporation and its health maintenance organization." In addition, subsection (d)(3) has been amended to include a denial to grant an exception. The Department has further clarified that failure to comply may result in action rather than will automatically so result.

Contact Person

Rodney C. Moyer, Director
Division of Health Care Plans
P O Box 90
Harrisburg, Pa. 17108
(717) 783-2547

The Department of Health finds:

(1) That public notice of intention to adopt regulations adopted by this order has been duly given under sections 201 and 202 of the CDL (45 P. S. §§ 1201 and 1202) and the regulations thereunder, 1 Pa. Code §§ 7.1 and 7.2.

(2) That the adoption of the regulations of the Department of Health in the manner provided in this order is necessary and appropriate for the administration and enforcement of the authorizing statutes.

(3) The Department of Aging has reviewed the proposed regulations and finds them acceptable.

The Department of Health, acting under the authorizing statutes, orders:

(A) The regulations of the Department of Health, 28 Pa. Code, are amended by adding Chapter 9, §§ 9.1, 9.2, 9.31, 9.32, 9.51 - 9.55, 9.71 - 9.77, and 9.91 - 9.97, to read as set forth in Annex A hereto.

(B) The Secretary of the Department of Health shall submit this order and Annex A hereto to the General Counsel for review and approval and to the Office of the Attorney General for review as to legality as required by law.

(C) The Secretary of the Department of Health shall duly certify this order and Annex A hereto and deposit the same with the Legislative Reference Bureau as required by law.

(D) This order shall take effect upon publication in the *Pennsylvania Bulletin*.

By the Department of Health

H. ARNOLD MULLER, M.D.,

Secretary

Fiscal Note: Fiscal Note H81-4 remains valid for the final adoption of the subject regulation.

Annex A

TITLE 28. HEALTH AND SAFETY PART I. GENERAL HEALTH CHAPTER 9. HEALTH MAINTENANCE ORGANIZATIONS

Contents

Sec.	
	Subchapter A. GENERAL INFORMATION
9.1	Applicability
9.2	Definitions
	Subchapter B. DEVELOPMENT OF A HEALTH MAINTENANCE ORGANIZATION
9.31	Certificate of need requirements
9.32	Preapplication development activities
	Subchapter C. APPLICATION FOR A CERTIFICATE OF AUTHORITY
9.51	Prohibition against uncertified health maintenance organizations

9.52	Content of application for certificate of authority
9.53	Review by the Department
9.54	Standards regarding approval of certificate of authority
9.55	Alternative application format

Subchapter D. CERTIFICATE OF AUTHORITY REQUIREMENTS FOR FOREIGN HEALTH MAINTENANCE ORGANIZATIONS (Reserved)

Subchapter E. OPERATIONAL STANDARDS FOR A HEALTH MAINTENANCE ORGANIZATION

9.71	Operational standards
9.72	Basic health services
9.73	Subscriber grievance systems
9.74	Quality assurance systems
9.75	Assurance of access of care
9.76	Professional staffing of health maintenance organizations
9.77	Subscriber rights

Subchapter F. CONTINUING SUPERVISION OF OPERATIONAL HEALTH MAINTENANCE ORGANIZATIONS

9.91	Annual reports
9.92	Quarterly reports
9.93	External quality assurance assessment
9.94	Departmental investigation
9.95	Federally qualified health maintenance organizations
9.96	Board composition
9.97	Exceptions

Subchapter G. PENALTY PROVISIONS (Reserved)

Subchapter H. CONTRACTS WITH PRACTITIONERS HOSPITALS, INSURANCE COMPANIES (Reserved)

Subchapter A. GENERAL INFORMATION

§ 9.1. Applicability.

This chapter shall be applicable to all persons who propose to undertake to establish, maintain, and operate a health maintenance organization within this Commonwealth, with the exception of health maintenance organization programs exempted under sections 16 and 17(b) of the act (40 P. S. §§ 1566 and 1567(b)).

§ 9.2. Definitions.

The following words and terms, when used in this chapter, shall have the following meanings unless the context clearly indicates otherwise:

Act — The Health Maintenance Organization Act (40 P. S. §§ 1551 - 1567).

Basic health services — Those health services, including as a minimum but not limited to emergency care, inpatient hospital and physician care, ambulatory physician care, and outpatient and preventive medical services; the term is elaborated on in § 9.72 (relating to operational standards regarding basic health services).

Certificate of authority — The document issued jointly by the Secretary and the Commissioner permitting a corporation to establish, maintain and operate a health maintenance organization.

Commissioner — The Insurance Commissioner of the Commonwealth.

Department — The Department of Health of the Commonwealth.

Federally qualified health maintenance organization — An entity which has been found by the Secretary of the United States Department of Health and Human Services to meet the requirements of § 1301 of the Public Health Service Act (42 U.S.C. § 300e).

Group practice HMO — An HMO that contracts with a medical group, partnership, or corporation composed of health professionals licensed to practice medicine or osteopathy as well as other health professionals necessary for the provision of health services.

Health maintenance organization (HMO) — An organized system which combines the delivery and financing of health care and which provides basic health services to voluntarily enrolled subscribers for a fixed prepaid fee.

Individual practice association (IPA) HMO — An HMO that contracts for delivery of services with a partnership, corporation, or association whose major objective is to enter into contractual arrangements with health professionals for the delivery of such health services.

Subscriber — An individual who is contractually entitled to receive basic health services from a health maintenance organization.

Secretary — The Secretary of Health of the Commonwealth.

Staff HMO — An HMO that delivers services through its own physicians who are paid employees (staff) of the HMO.

Primary care physician — A physician who supervises, coordinates, and provides initial and basic care to members; initiates their referral for specialist care; and maintains continuity of patient care.

Subchapter B. DEVELOPMENT OF A HEALTH MAINTENANCE ORGANIZATION

§ 9.31. Certificate of need requirements.

Corporations seeking to develop health maintenance organizations may be subject to the provisions of the Health Care Facilities Act (35 P.S. §§ 448.101 — 448.904) and Chapter 401 (relating to Certificate of Need program). Applications for a certificate of authority under the act will be examined to ensure compliance with Certificate of Need requirements.

§ 9.32. Preapplication development activities.

Corporations in the process of developing a health maintenance organiza-

tion are urged, but not required, to periodically inform the Department of their developmental activities and to make use of Department technical advice and assistance as authorized by section 2 of the act (40 P.S. § 1552).

Subchapter C. APPLICATION FOR A CERTIFICATE OF AUTHORITY

§ 9.51. Prohibition against uncertified health maintenance organizations.

No corporation shall solicit enrollment of subscribers, enroll subscribers, or deliver prepaid basic health care services by, through, or in a health maintenance organization until it has received a certificate of authority to operate and maintain such health maintenance organization from the Secretary and the Commissioner.

§ 9.52. Content of application for certificate of authority.

Each application for a certificate of authority under the act shall be made to the Secretary and the Commissioner in writing. That part of the application directed to the Secretary shall contain the following information:

(1) A copy of the basic organizational document of the applicant organization, such as the articles of incorporation, and all amendments thereto.

(2) A copy of the bylaws, rules and regulations, or similar documents regulating the conduct of the internal affairs of the applicant corporation.

(3) A list of the names, addresses, and official positions of the board of directors of the applicant corporation and of persons who are to be responsible for the conduct of the affairs of the applicant — including but not limited to the Executive Director or President, Medical Director, Director of Marketing, and Director of Finance.

(4) A description of the service area of the proposed health maintenance organization — including geographic boundaries, demographic data, and identification of population groups which would be sources of prepayment.

(5) A copy of the applicant corporation's proposed contracts with subscribers and groups of subscribers, setting forth the corporation's contractual obligations to provide basic health services.

(6) A copy of the applicant corporation's contracts with physicians, groups of physicians organized on a group-practice or individual-practice basis, hospitals, skilled nursing facilities,

and other providers of health care services enabling it to provide basic health services to a voluntarily enrolled population.

(7) A copy of any contract with any individual, partnership, association, or corporation for the performance on its behalf of any necessary functions including but not limited to marketing, enrollment, and administration and of any contract with an insurance company, hospital plan corporation, or professional health service corporation for the provision of insurance or indemnity or reimbursement against the cost of health care services provided by the health maintenance organization.

(8) A detailed description of the applicant corporation's proposed grievance resolution system whereby the complaints of its subscribers may be acted upon promptly and satisfactorily.

(9) A detailed description of the applicant corporation's arrangements for an ongoing quality-of-health-care assurance program.

(10) A detailed description of the applicant corporation's potential ability to assure both the availability and accessibility of adequate personnel and facilities to serve enrolled subscribers in a manner enhancing availability, accessibility, and continuity of services, including information regarding proposed practice site locations and hours of operation.

(11) A detailed description of reasonable incentives for cost control within the structure and function of the proposed health maintenance organization.

(12) A brief description of Federal grant or loan funds received by the applicant corporation for the purposes of developing a federally qualified health maintenance organization.

(13) A copy of the applicant corporation's most recent financial statement.

(14) A description of the applicant corporation's capability to collect and analyze necessary data relating to the utilization of health care services by enrolled subscribers.

(15) A copy of proposed general subscriber literature.

(16) A job description for the position of medical director.

(17) A procedure for referral of subscribers to nonparticipating specialists.

(18) Written procedures for payment of emergency services provided by other than a participating provider.

(19) A description of the manner in which subscribers will be selected to meet the statutory requirement that 5 of the board members be subscribers.

(20) A description of the system established to ensure that the records of the corporation pertaining to its operation of a health maintenance organization are identifiable and distinct from other activities that corporation may engage in.

(21) A copy of the written procedures regarding frequently utilized services required by § 9.75(e) (relating to operational standards regarding assurance of access to care).

(22) Any other information that the applicant corporation may wish to submit which reasonably relates to its capability of operating and maintaining a health maintenance organization.

§ 9.53. Review by the Department.

(a) Before the Department approves issuance of a certificate of authority, it will conduct a thorough assessment to ascertain whether the proposed health maintenance organization, the plan under which it proposes to operate, and the services which it proposes to provide are consistent with the purposes and provisions of the act and this chapter.

(b) Within 10 business days of receiving an application for a certificate of authority, the Department will determine whether the information submitted is complete. If the Department determines that the information is not complete and that additional information is required, it will send a request as soon as possible in writing to the applicant corporation stating specifically what information is needed. A copy of the request will be sent to the Commissioner.

(c) The application for a certificate of authority will not be considered complete until the additional information is received by the Department.

(d) The Department may visit or inspect the site or proposed site of the health maintenance organization's facilities to ascertain its capability to carry out its required functions.

(e) Upon receipt of an application for a certificate of authority, the Department will publish notification of receipt of the filing in the *Pennsylvania Bulletin* in order to provide an opportunity for public comment.

(f) The Department may hold a public hearing to obtain additional information about a proposed health maintenance organization. The De-

partment, whenever possible and appropriate, will attempt to hold joint hearings with the Insurance Department.

(1) If the Department decides to hold a public hearing, notification in writing will be provided to the applicant corporation by certified mail at least 10 business days prior to the hearing.

(2) Notice of the hearing will also be published in the *Pennsylvania Bulletin* at least 10 days prior to the hearing.

(3) The hearing will be conducted as soon as possible, but no earlier than 10 business days after written notice has been provided to the applicant corporation.

(g) The Department will confer with and coordinate its investigation with the Commissioner.

(h) Within 90 days of receipt of a completed application for a certificate of authority, the Secretary and Commissioner will jointly do either of the following:

(1) Approve the application and issue a certificate of authority; or,

(2) Disapprove the application, specifying in writing the reasons for such disapproval; any disapproval of an application may be appealed in accordance with 2 Pa. C.S. §§ 501 — 508 and 701 — 704 (relating to administrative agency law).

§ 9.54. Standards regarding approval of certificate of authority.

Each application for a certificate of authority will be reviewed to ensure that the applicant corporation and proposed health maintenance organization are capable both initially and on an ongoing basis to meet the minimum operating standards found in Subchapter E (relating to operational standards for a health maintenance organization).

§ 9.55. Alternative application format.

With prior permission of the Department an applicant corporation may submit, in lieu of the information and format required in § 9.52 (relating to content of application for certificate of authority), a copy of its Federal qualification application appropriately annotated and referenced to the submission requirements of the chapter.

SUBCHAPTER D. CERTIFICATE OF AUTHORITY REQUIREMENTS FOR FOREIGN HEALTH MAINTENANCE ORGANIZATIONS (Reserved)

SUBCHAPTER E. OPERATIONAL STANDARDS FOR A HEALTH MAINTENANCE ORGANIZATION

§ 9.71. Operational standards.

Each corporation receiving a certificate of authority to establish and operate a health maintenance organization under the act shall provide quality health care services in a cost-effective manner to voluntarily enrolled subscribers by meeting the minimum standards set forth in this subchapter:

§ 9.72. Basic health services.

(a) A health maintenance organization shall provide at least the following basic health services:

(1) Emergency care. Professionally health services medically necessary immediately to preserve life or stabilize health, available on an inpatient or outpatient basis 24 hours per day, 7 days per week.

(2) Ambulatory physician care. Medically necessary and preventive health services performed, prescribed or supervised by physicians for patients who are not confined to bed in an institution or at home. These services may be provided in a nonhospital based health care facility, at a hospital, or in a physician's office.

(3) Inpatient hospital care. Medically necessary hospital service affording inpatient treatment to subscribers in general hospital for a minimum of 9 days per contract or calendar year. Hospital services include room and board; general nursing care; special diets when medically necessary; use of operating room and related facilities; use of intensive care unit and services; x-ray, laboratory, and other diagnostic tests; drugs, medications, biologicals; anesthesia, and oxygen services; special duty nursing when medically necessary; physician therapy, radiation therapy, and inhalation therapy; administration of whole blood and plasma; and short-term rehabilitation services.

(4) Inpatient physician care. Generally accepted and medically necessary health services performed, prescribed or supervised by physicians within a hospital for registered bed patients, including diagnostic and therapeutic care.

(5) Outpatient and preventive medical services. Services, such as well baby care, immunizations, and periodic physical examinations, provided with the goal of protection against and early detection and minimization of the ill effects and causes of disease or disability.

(b) A health maintenance organization shall provide basic health services to its subscribers as needed and without unreasonable limitations as to time and cost. Nominal copayments may be imposed upon basic health services, subject to the following conditions.

(1) To insure that copayments are not a barrier to the utilization of health services or membership in the organization, a health maintenance organization shall neither impose copayment charges that exceed 50% of the total cost of providing any single service to its subscribers nor 20% of the total cost of providing all basic health services.

(2) No copayment may be imposed on any subscriber covered under his contract in any calendar year when the copayments made by the subscriber in the calendar year total 50% of the total annual premium cost which the subscriber would be required to pay if enrolled under an option with no copayments. The subscriber must demonstrate that copayments in that amount have been paid during the calendar year.

(c) Reasonable exclusions, such as are customarily found in group health insurance policies, will be permitted. Examples of reasonable exclusions are cosmetic surgery unless medically necessary, custodial or domiciliary care, and durable medical equipment for home use.

(d) A health maintenance organization may provide in addition to basic health services, other health services such as cosmetic surgery, prescription drug coverage, dental coverage, mental health benefits, and similar services which a voluntarily enrolled population may require to maintain physical and mental health.

§ 9.73. Subscriber grievance systems.

An HMO shall have a written grievance procedure for prompt and effective resolution of subscriber grievances. The grievance procedure shall include the following elements:

(1) There shall be an initial level of investigation and review of any grievance.

(i) The initial review shall be conducted by a committee consisting of one or more individuals who may be employees of the health maintenance organization.

(ii) The initial review shall provide the opportunity for the subscriber and any other party of interest to present written data pertinent to the grievance.

(iii) The decision of the initial review committee shall be binding unless the subscriber appeals the decision.

(iv) The subscriber shall be notified in writing of his right to appeal the decision to a second level review committee.

(2) A subscriber shall have the right to appeal a decision of the initial review committee to a second level of review.

(i) The second level of review shall be conducted by a committee established by the board of directors of the health maintenance organization.

(ii) At least 1/3 of the members of the committee shall be subscribers of the health maintenance organization.

(iii) The decision of the second level review committee shall be binding unless the subscriber appeals the decision depending upon the nature of the grievance to the Secretary or the Commissioner.

(iv) The subscriber shall be notified in writing of his right to appeal a decision of the second level of review committee.

(v) The second level review committee shall have written procedures for investigating grievances, for conducting formal hearings, and for utilizing informed consultants to resolve grievances.

(3) An oral complaint which cannot be resolved informally shall be presented in writing according to paragraphs (1) and (2) before it shall be considered a formal grievance.

(4) The health maintenance organization shall specify reasonable time limits for disposition of grievances at each level of review.

(5) The health maintenance organization shall include a description of the grievance system in subscriber contracts.

(6) The health maintenance organization shall have a separate and additional form notifying subscribers of the existence of and their rights within the grievance system. This form shall be distributed to subscribers at least annually. Publication of this information in a member newsletter published by the health maintenance organization shall be sufficient to meet this paragraph.

(7) At any stage of the grievance process, at the request of a subscriber, the health maintenance organization shall appoint a member of its staff who has no direct involvement in the case

to represent the subscriber. A subscriber presenting a grievance shall be specifically notified of his right to have such a staff member appointed to assist him.

(8) The health maintenance organization shall maintain records of all grievances and shall include in its annual reports to the Department a description of the total number of grievances handled, a compilation of the causes underlying the grievances, and the resolution of the grievances. See § 9.91 (relating to annual reports).

§ 9.74. Quality assurance systems.

(a) A health maintenance organization shall have a written procedure to provide ongoing review, analysis, assessment, and subsequent actions for improvement of the quality of health care services delivered to its subscribers. This procedure shall include at least the following elements:

(1) Medical records shall be maintained in a current, detailed, and comprehensive manner which conforms with good professional medical practice, permits effective quality assurance review, and facilitates continuity of care.

(2) A procedure shall be specified to assure that only those services which represent proper utilization of health care facilities and conform with contractual provisions are provided.

(b) Review of the quality of care shall not be limited to technical aspects of care alone but shall also include availability, accessibility, and continuity of care provided to members.

(c) The results of quality assurance activities shall be made known to participating providers in a manner designed to facilitate improvement in the quality of service delivered, and which is approved by the Department.

(d) At least once a year, a report on quality assurance activities — including studies undertaken, results, subsequent actions, and aggregate data on utilization and quality of services rendered to subscribers — shall be presented to the board of directors.

(e) Data on the utilization of health care services shall be collected and shall be analyzed periodically to identify for further in-depth investigation potential over-utilization, under-utilization, or misutilization of health care services by members or providers. Aggregate utilization data shall be reported quarterly to the Secretary. See § 9.92 (relating to quarterly reports).